



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 30 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil DCI 50534/81901. Memorandum of
Telephone Conversation Held 12/11/91. ISK Biotech
Corporation Letter Dated 12/31/91.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C) *Mike Flood*

THROUGH: Elizabeth T. Haeberer, Section Chief *Elizabeth T. Haeberer*
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

TO: Andrew Ertman
Reregistration Branch
Special Review and Reregistration Division (H7508W)

ISK Biotech, in a letter addressed to this reviewer by Mr.
Jerry R. Lucietta, has submitted its summary of a telephone
conversation held on December 11, 1991.

In that conversation, ISK Biotech Corp. discussed residue
data requirements on bananas to be imported to the U.S. The
company proposed to conduct one field trial in Columbia, Panama,
Honduras and Guatemala and two field trials in Costa Rica. These
countries represent about 70% of the bananas grown for export in
the U.S. However, field trials in Ecuador, which accounts for
most of the remaining 30%, were not planned because of
difficulties in assuring GLP compliance. I agreed that the
proposed field trial plan would be acceptable. During this
conversation the particular fungicide was not identified as
chlorothalonil. Although the protocol should apply to
chlorothalonil, SRRD should verify that our recommendation is
consistent with the DCI.

I also noted that we would not automatically reject a study
not conducted under GLP. Such a study would be acceptable if the
reasons for non compliance did not affect the actual residue
data. However each non-GLP study would have to be examined on an
individual basis. My interpretation differs from ISK Biotech's
understanding that "if a non-GLP study in Ecuador was conducted
and submitted it would not be rejected and could be considered as

additional data." ISK Biotech's interpretation should be corrected.

cc: SF, RF, Circu., Reg. Std. File, PIB/FOD(C.Furlow), M.Flood,
C.Giles-Parker(H7505C).
H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):1/29/92.
RDI:SectionHead:ETHaeberer:1/24/92:BranchSeniorScientist:RALoranger:
1/27/92.